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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,491	11/21/2001	Gary S. Hahn	Sensory 0003.CON3	9928

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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,491

Applicant(s)

HAHN ET AL

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-25, 28-32, 41 and 46-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 26, 27, 33-40 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/21/05, 08/22/05, 10/6/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of amendment filed on January 25, 2005. Claims 1-65 are pending, of which claims 2, 4-25, 28-32, 41, and 46-65 have been withdrawn from consideration. Claim rejections made under 35 U.S.C. § 112, first paragraph, as indicated in the previous Office action dated May 27, 2003, are withdrawn in view of claim amendment made by applicants. Obvious double patenting rejection as indicated in the same Office action is withdrawn in view of applicants' remarks. Claim rejections made under 35 U.S.C. § 103 (a) as indicated in the same Office action are maintained for the reasons of record. New rejection is made in view of the disclosure made by applicants.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on January 21, 2005, August 22 2005, and October 6, 2005 were filed after the mailing date of the non-final Office action mailed on May 27, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 26, 27, 33-36, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bristow et al. (EP 0346957) ("Bristow").

The instant invention is directed toward a composition comprising 0.5-10% aqueous soluble divalent strontium cation and a suitable topical vehicle.

Bristow discloses a toothpaste composition for sensitive teeth, comprising 3 % of strontium acetate and a surfactant and an emulsifier (sodium lauryl sulphates), a nonionic surfactant and emulsifier (sorbitol syrup), thickener (sodium carboxymethylcellulose), preservatives (formalin), an active agent (sodium monofluorophosphate and hydroxyapatite), and antibiotic (chlorhexidine digluconate). See Example 3-6. See instant claims 1, 3, and 26, 33, 34, 35, 42, 43. The reference also teaches using nonionic surfactants. See p. 3, lines 5-9. See instant claim 27.

The claimed invention is directed to a composition. The Examiner respectfully points out that the recitation of the intended use of the claimed invention must result in a structural difference between the present composition and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The Examiner respectfully points out that the intended use of the instant claims is not given patentable weight. The phrases "for reducing skin irritation in animals" and "wherein said topical formulation is packaged

with instructions directing the administration of said composition to the skin of an animal subject" are considered as the intended use of the composition.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biener (4,943,432).

Biener teaches a salt mixture comprising strontium for the treatment of psoriasis and other skin diseases (abstract). The salt mixture contains from 0.02-10.5 g/Kg strontium ion (col. 2, line 32). Water is taught as a medium (col. 3, lines 53-55). Additional ingredients that may be in the composition are salicylic acid (an anti-acne agent/beta-hydroxy acid), emollients, etc (col. 3, lines 38-44), natural and synthetic gums and colloids (col. 4, lines 9-15) and glycol (col. 4, lines 21). For preservatives, see column 5, line 29. The reference lacks an exemplification of the percent weight of strontium.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the strontium as comprising 0.5-10% of the composition because it is taught that strontium can comprise 0.02-10.5 g/Kg of the salt mixture and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233.

The Examiner respectfully points out that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The Examiner respectfully points out that the intended use of the instant claims is not given patentable weight. The phrases "for reducing skin irritation in animals" and "wherein said topical formulation is packaged with instructions directing the administration of said composition to the skin of an animal subject" are considered as the intended use of the composition.

The Examiner respectfully points out that the limitations in the instant independent claims regarding the properties of the compositions are not given patentable weight, as a composition comprising the same components must have the same properties, i.e., reducing skin irritation.

Claims 3, 26, 33-38, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener (4,943,432) as applied to claim 1 above, and further in view of D'Alelio (4,477,439).

Biener is applied as discussed above. The reference fails to teach a lotion and surfactants.

D'Alelio teaches a composition for reducing soreness of irritated skin comprising

strontium. The formulation can be in the form of a powder, an aqueous suspension, a paste, an ointment, or a cream (see abstract). Additional ingredients are viscosity modifiers, dispersing agents (surfactants), preservatives, and anesthetics (col. 1, lines 49-51). Colorants and perfumes are disclosed at column 2, line 6. For anionic surfactants. See column 1, lines 59-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Biener in the form of a lotion, as taught by D'Alelio, because Biener teaches his compositions in the form of an aqueous solution, a gel, a salve, and powder, and D'Alelio teaches powders, aqueous suspensions, ointments (salves), and creams (lotions) as interchangeable cosmetic forms for compositions comprising strontium; thus, one of skill in the art would be motivated to teach the composition of Biener in the form of a lotion (cream) because D'Alelio teaches aqueous solutions, salves, powders, and creams (lotions), as interchangeable.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener in view of D'Alelio as applied to claims 1, 3, 26, 33, 34, 35, 37, 38, 42 above, and further in view of Yu et al. (2001/0016604).

Biener and D'Alelio are applied as discussed above. The references do not teach alpha-hydroxy acids.

Yu et al. teach additives enhancing topical actions of therapeutic agents. Hydroxy acids are taught as substantially enhancing the therapeutic efficacy of cosmetic and pharmaceutical agents in topical treatment of cosmetic conditions, dermatologic

disorders or other afflictions. Specifically, lactic acid and glycolic acid are taught as normalizing the disturbed keratinization in psoriasis. See [0008], [0136]-[0139].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycolic acid, as taught by Biener, to the composition of Yu et al. because of the expectation of achieving a composition that synergistically treats psoriasis by normalizing the disturbed keratinization in psoriasis.

Claims 27, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener in view of D'Alelio as applied to claims 1, 3, 20, 33, 34, 35, 37, 38, 42 above, and further in view of McAtee (5,665,364).

Biener and D'Alelio are applied as discussed above. The references do not teach polysorbate 60 (Applicant's elected surfactant species) or emulsifiers.

McAtee teaches compositions for topical delivery of active ingredients. Emulsifiers are taught as useful for emulsifying the various carrier components of the topical cosmetic compositions. Nonionic, cationic, anionic, and zwitterionic emulsifiers, and combinations thereof are taught as suitable emulsifiers that can be added to the composition. Polysorbate 60 is specifically taught as a preferred emulsifier. See col. 16, line 63 - col. 17, line 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add polysorbate 60, as taught by McAtee, to the composition of the combined references because of the expectation of achieving a composition that effectively emulsifies the various carrier components of the composition.

Response to Arguments

Applicant's arguments filed January 21, 2005 have been fully considered but they are not persuasive.

Applicants assert that the amount of strontium cation in the Biener composition is minor in relation to the amount of aqueous-soluble divalent strontium cation in the present invention. That difference has been acknowledged and addressed by the examiner in the previous rejection. And yet the obviousness rejection was made on the rationale that the discovery of workable weight amount of the active ingredient would have been within the ordinary skill in the art.

Applicants argue that D'Alelio teaches away from the present invention because the strontium salts used in D'Alelio are insoluble in water. In response, examiner notes that the use of water-soluble strontium salts are already taught in the Biener reference. The reason for combining the Biener/D'Alelio references was that a skilled artisan would have found it obvious to formulate a lotion in view of the combined teachings of the references. Furthermore, applicants assert that D'Alelio teaches away from adding an irritant ingredient. Again, the Biener reference teaches the addition of alpha-hydroxy acids with the strontium salts in making a topical composition, and D'Alelio reference is cited to show that lotion is an obvious vehicle form of a topical composition.

Conclusion

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 21, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

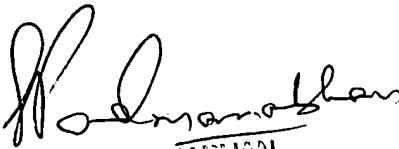
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



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